

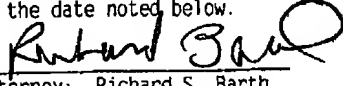
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**IN THE UNITED STATES PATENT
AND TRADEMARK OFFICE**

Patent No. : 7,335,765
Patentees : Masakatsu KANEKO et al.
Issue Date : February 26, 2008
Serial No. : 09/925,673
Filed : August 9, 2001
For : NOVEL NUCLEOSIDE AND
OLIGONUCLEOTIDE ANALOGUES
Art Unit : 1623
Examiner : Ganapathy KRISHNAN
Docket No. : 01376CIP/HG
Confirm. No.: 4630
Customer No.: 01933

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Attorney: Richard S. Barth

Dated: OCTOBER 8, 2008

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**RESPONSE TO THE AUGUST 12, 2008 DECISION ON THE REQUEST
FOR RECONSIDERATION OF DECISION ON APPLICATION FOR
PATENT TERM ADJUSTMENT FILED FEBRUARY 14, 2008**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

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S I R :

This is a response to the August 12, 2008 DECISION which
dismissed the REQUEST FOR RECONSIDERATION OF DECISION ON
APPLICATION FOR PATENT TERM ADJUSTMENT filed February 14, 2008
(hereinafter referred to as "the August 12, 2008 DECISION") in
the above-identified patent.

The August 12, 2008 DECISION was rendered in light of the "APPLICATION FOR PATENT TERM ADJUSTMENT INCLUDING REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT INDICATED IN AN ISSUED PATENT (37 CFR §1.705(d))" filed March 20, 2008.

The August 12, 2008 DECISION gave patentees two months from the mailing date of the August 12, 2008 DECISION to respond, i.e., by October 12, 2008.

A. BACKGROUND

1. A Corrected Notice of Allowance and Fee(s) Due mailed April 5, 2008 **required** that the Issue Fee be paid by July 5, 2005. Other than paying the Issue Fee, there were no further requirements to be met. The Issue Fee was paid on June 27, 2005.

2. Almost one year after the aforesaid Issue Fee was paid, the USPTO issued a "NOTICE OF WITHDRAWAL FROM ISSUE UNDER 37 CFR 1.313(c)" (undated, but mailed on June 22, 2006) (hereinafter referred to as the "NOTICE OF WITHDRAWAL").

The NOTICE OF WITHDRAWAL erroneously stated that the Issue Fee had not been paid. As noted hereinabove, the Issue Fee was paid on June 27, 2005.

The NOTICE OF WITHDRAWAL erroneously stated that the withdrawal was under 37 CFR 1.313(c) (i.e., upon petition by applicants). As pointed out in patentees' LETTER RE: NOTICE OF WITHDRAWAL FROM ISSUE filed July 11, 2006, the application was withdrawn from issue by the initiative of the USPTO and therefore was under 37 CFR 1.313(b), not 37 CFR 1.313(c).

3. More than one year after the aforesaid Issue Fee was paid, an Office Action was mailed on August 1, 2006, which rejected claims 2, 4, 5 and 6 under 35 USC 112, second paragraph; and rejected claims 1-7, 37-45, 55, 62-65, 70, 72, 76 and 111 under 35 USC 102 and 35 USC 103 over disclosure in the specification of USP 6,794,499 to Wengel et al.

USP 6,794,499 to Wengel et al. was cited in patentees' INFORMATION DISCLOSURE STATEMENT filed February 17, 2005 (hereinafter referred to as the "February 17, 2005 IDS"). In the February 17, 2005 IDS, it was stated that USP 6,794,499 issued from application Serial No. 09/152,059, and that US 2002/0068708 (the published application of Serial No. 09/152,059) was cited in patentees' INFORMATION DISCLOSURE STATEMENT filed August 17, 2004 (hereinafter referred to as the "August 17, 2004 IDS"). USP 6,794,499 and US 2002/0068708 are hereinafter referred to collectively as "Wengel et al."

The Examiner considered and made of record said August 17, 2004 IDS and February 17, 2005 IDS by initialing each cited publication.

Said August 17, 2004 IDS also identified USP 6,670,461, US 2003/0134808 and US 2003/0144231, which are patent family members with the aforescribed Wengel et al. USP 6,794,499 and US 2002/0068708. All these U.S. patent documents should have the same specification and disclose the same subject matter relied upon in the rejection of claims under 35 USC 102 and 35 USC 103 in the August 1, 2006 Office Action.

It is therefore respectfully submitted that the USPTO unduly delayed, for the first time, in applying the Wengel et al. specification to reject the patentees' claims in the August 1, 2006 Office Action, after the USPTO withdrew the above-identified application from issue more than one year after patentees paid the Issue Fee on June 27, 2005.

At the top of page 4 of the August 12, 2008 DECISION, the following was stated:

"It is regretted that more than a year elapsed from the withdrawal of the application from issue until the mailing of the Office Action on August 1, 2006."

4. An AMENDMENT UNDER 37 CFR 1.111, which (i) made minor editorial corrections to several claims and (ii) traversed said rejections under 35 USC 102, 35 USC 103 and 35 USC 112, was filed November 8, 2006.

5. A FINAL rejection was mailed February 7, 2007, which withdrew the 35 USC 112 rejection and again rejected all of the claims under 35 USC 102 and 35 USC 103 over said Wengel et al. USP 6,794,499.

6. A RESPONSE UNDER 37 CFR 1.116 was filed May 7, 2007, which did not amend claims, but instead presented arguments to traverse the rejections under 35 USC 102 and 35 USC 103 (the only remaining rejections).

7. A NOTICE OF ALLOWANCE AND ISSUE FEE(S) DUE was mailed July 26, 2007, which required only that a Issue Fee Transmittal be filed. The Determination of Patent Term Adjustment Under 35

U.S.C. 154(b) attached to the July 26, 2007 NOTICE OF ALLOWANCE AND ISSUE FEE(S) DUE indicated a patent term adjustment of 195 days.

8. An APPLICATION FOR PATENT TERM ADJUSTMENT INCLUDING REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT INDICATED IN NOTICE OF ALLOWANCE (37 CFR §1.705) was filed September 6, 2007 (hereinafter referred to as the "APPLICATION FOR PATENT TERM ADJUSTMENT filed September 6, 2007") to request that the aforesaid 195 days of patent term adjustment be changed to add 278 days, i.e., for a total of 473 days of patent term adjustment. The request for 278 days of additional patent term adjustment was pursuant to 35 USC 154(b)(1)(A)(ii) and 37 CFR 1.702(a)(2) for the period from four months after payment of the Issue Fee on June 27, 2005 to the mailing of the August 1, 2006 Office Action.

9. An Issue Fee Transmittal was mailed to the USPTO on September 27, 2007.

10. A DECISION ON APPLICATION FOR PATENT TERM ADJUSTMENT from the USPTO dated January 4, 2008 dismissed the APPLICATION FOR PATENT TERM ADJUSTMENT filed September 6, 2007.

11. An ISSUE NOTIFICATION from the USPTO dated February 6, 2008 stated that the patent (USP 7,335,765) would issue on February 26, 2008. Since February 26, 2008 is four months and thirty days from the submission of the Issue Fee Transmittal on September 27, 2007, patentees were afforded thirty days of patent term adjustment, in addition to the 195 days of patent term adjustment set forth in the July 26, 2007 Determination of Patent Term Adjustment.

B. REBUTTAL OF THE REASONS FOR DISMISSAL
SET FORTH IN THE AUGUST 12, 2008 DECISION

1. 35 USC 154(b) (1) (A) (ii); 37 CFR 1.702(a) (2)

Patentees have asserted in their aforesaid papers filed September 6, 2007 and February 14, 2007 that 35 USC 54(b) (1) (A) (ii) and its corresponding section in the rules, 37 CFR 1.702(a) (2), provide a proper basis for affording additional days of patent term adjustment. This position was dismissed in each of the USPTO DECISIONS dated January 4, 2008 and August 12, 2008.

35 USC 154(b) (1) (A) (ii) refers to delays due to the failure of the Patent and Trademark Office to

"(ii) respond to a reply under section 132...within 4 months after the date on which the reply was filed."

35 USC 132(a) provides as follows:

"Whenever, on examination, any claim for a patent is rejected, or any objection or **requirement** made, the Director shall notify the applicant thereof, stating the reasons for such rejection, or objection or **requirement**." (emphasis added)

On page 2, lines 10 to 11 in the January 4, 2008 DECISION, it is stated "First of all, the relevant section to consider is 37 CFR 1.702(a) (4), not (a) (2)." No reason or authority was set forth in the January 4, 2008 DECISION why 37 CFR 1.702(a) (2) was

not the relevant section. Thereafter, the January 4, 2008 DECISION was made based solely on 37 CFR 1.702(a)(4).

In the last full paragraph on page 3 of the August 12, 2008 DECISION, the position was taken that the payment of an Issue Fee is not a "reply" under 35 USC 132. No authority was set forth for such position.

35 USC 102(a) refers not only to a rejection or an objection, but also to a **requirement**.

As asserted in patentees papers filed September 6, 2007 and February 14, 2008, the USPTO failed to respond within four months from the aforesaid payment of the Issue Fee on June 27, 2005, as required by 37 CFR 1.702(a)(2) ("Respond to a Reply under 35 USC 132..."). The payment of the issue Fee on June 27, 2005 is respectfully submitted to have been made in compliance with a "requirement" under 35 USC 132(a), i.e., the **requirement** to pay the Issue Fee. The USPTO did not respond to the aforesaid June 27, 2005 payment of the Issue Fee until the mailing of the August 1, 2006 Office Action.

As noted above, the USPTO DECISIONS of January 4, 2008 and August 12, 2008 did not cite any authority to rebut patentees' position that the payment of the Issue Fee on June 27, 2005 was a requirement under 35 USC 132, and therefore it is respectfully submitted that 37 CR 1.702(a)(2) is an applicable basis for affording additional days of patent term adjustment to the patentees.

2. 35 USC 154(b)(1)(A)(iv); 37 CFR 1.702(a)(4)

Patentees have asserted in their aforesaid papers filed February 4, 2008 and March 20, 2008 that 35 USC 154(b)(1)(A)(iv)

and its corresponding section in the Rules, 37 CFR 1.702(a)(4), provide a proper basis for affording additional days of patent term adjustment.

35 USC 154(b)(1)(A)(iv) states as follows:

"(iv) issue a patent within 4 months after the date on which the issue fee was paid under section 151 and all outstanding requirements **were satisfied**," (emphasis added)

In the last paragraph on page 2 of the January 4, 2008 DECISION, and the middle of page 2 and at the top of page 5 of the August 12, 2008 DECISION, it was asserted that the following was "stated" in the final rule:

"...the date the issue fee was paid and all outstanding requirements were satisfied is the later of the date the issue fee was paid or the date all outstanding requirements were satisfied. However, if prosecution in an application is reopened after allowance (see MPEP 1308), all outstanding requirements are not satisfied until the application is again in condition for allowance as indicated by the issuance of a new notice of allowance under 35 U.S.C. 151 (see MPEP 1308). See *Changes to Implement Patent Term Adjustment under Twenty-Year Patent Term; Final Rule*, 65 Fed. Reg. 54366 (September 18, 2000)."

It is respectfully submitted that the above quote represents only a comment in an OG Notice and is not supported by a statute, a USPTO rule, a cited precedent or a MPEP provision. Moreover, such quoted passage does not distinguish between a withdrawal from issue on the initiative of the USPTO (as in the case at

hand) or a withdrawal from issue based on an applicant's petition. It is therefore respectfully submitted that the above quote is not relevant with respect to the case at hand.

Furthermore, the instant case prosecution was opened not just after allowance, but, instead, was reopened after the Issue Fee was paid and **and all outstanding requirements were met.** Therefore, the above quoted passage is not applicable to this case.

It is noted that a possible "requirement" in a Notice of Allowability could be a requirement to submit a new drawing or a requirement to provide a statement of microorganism deposit. However, in the case at hand, there was no USPTO requirement, other than paying the Issue Fee.

As stated above, 35 USC 154(b)(1)(A)(iv) provides that if a patent is not issued within four months from the date the Issue Fee was paid and all outstanding requirements **were** satisfied, the term of a patent shall be extended.

The term "were" in 35 USC 154(b)(1)(A)(iv) is in the past tense. Thus, to satisfy the statute, if there is no outstanding requirement other than the requirement to pay the Issue Fee, once the Issue Fee is paid, the USPTO must issue the patent within four months and any delay by the USPTO is to be restored to the applicant. If there is an outstanding requirement at the time an Issue Fee is due, then the time within which the USPTO must act is within the later of compliance with the issue Fee payment or the requirement is met. If the USPTO wanted to issue a new requirement after the Issue Fee was paid and all requirements "were" met, it had one of the following two paths open to it: (1) it could withdraw the application from issue and do what it did in this case, but, according to the statute, the USPTO must restore the delay of more than four months to the patentee or (2)

the USPTO could issue the patent (with no need to restore any time to the patentee) and immediately order an ex parte reexamination for the prior art it wanted to apply.

The aforesaid interpretation comports with the intent of the statute which, as stated in the introduction to part (b) of 35 USC 154 quoted above, is to be a "GUARANTEE OF PROMPT PATENT AND TRADEMARK OFFICE RESPONSES."

The USPTO DECISIONS of January 4, 2008 and August 12, 2008 did not set forth any outstanding requirement that needed to be met after the Issue Fee was paid on June 27, 2005.

It is further respectfully submitted that the withdrawal from issue was improper because it did not set forth one of the reasons provided for in 37 CFR 1.313(b). See MPEP 1308, which states as follows:

"Any notice withdrawing an application from issue after payment of the issue fee must specify which of the conditions set forth in 37 CFR 1.313(b) (1) through (4) exists and thus warrants withdrawal of the application from issue."

Patentees wish to emphasize the following:

(i) on the date that the Issue Fee was paid, i.e., June 27, 2005, in reply to the April 5, 2008 Corrected Notice of Allowance, all outstanding requirements had been satisfied;

(ii) prior to the Notice of Withdrawal from Issue on June 22, 2006, the USPTO sent no notice which required the satisfaction of any outstanding requirements;

(iii) the Notice of Withdrawal of June 22, 2006 did not set forth any outstanding requirements that were not met; and

(iv) the mailing of a Non-Final Rejection on August 1, 2006 was the first action after the payment of the Issue Fee.

Accordingly, from June 27, 2005 to August 1, 2006, all outstanding requirements were satisfied. If the USPTO considered that any outstanding requirements were not satisfied, the USPTO should have mailed a Notice within four months from the date the Issue Fee was paid.

3. ALTERNATE BASIS FOR PATENT TERM ADJUSTMENT

It is considered that a rationale for the position stated in the 65 Fed. Reg. 54366 statement quoted in the August 12, 2008 DECISION and quoted hereinbefore that if prosecution in an application is reopened after allowance "...all outstanding requirements are not satisfied until the application is again in condition for allowance..." would be that the earlier issued Notice of Allowance and Issue(f) Due mailed April 5, 2005 was void *ab initio*. Based on the rationale discussed hereinabove and considering that the Corrected Notice of Allowance and Fee(s) Due mailed April 5, 2005 was void *ab initio*, the term of USPTO delay would start four months after patentees completed the requirements which placed the application in condition for allowance prior to April 5, 2005.

A. CONCLUSION

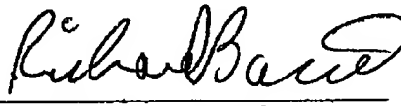
The USPTO did not act promptly in this application, as acknowledged at the top of page 4 of the August 12, 2008 DECISION. Following the spirit of the law to GUARANTEE ... PROMPT PATENT AND TRADEMARK RESPONSES, it is respectfully submitted that patentees be afforded additional days of patent term adjustment as previously requested.

Reconsideration and the granting of the additional days of patent term adjustment as previously requested are respectfully requested.

If any fees are required in connection with this paper, please such fees to Deposit Account No. 06-1378.

Respectfully submitted,

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